

REMARKS

Reconsideration and allowance are respectfully requested. Claims 1-2, 7-20, 24-28 and 31-32 are pending. In the Notice of Non-Compliant Amendment, it was alleged that "the last claim set of record" is December 7, 2006. This is incorrect. An after-final Amendment was filed on September 5, 2007. But its entry was denied in the Advisory Action mailed September 12, 2007. Then in the Request for Continued Examination filed on October 10, 2007, the after-final Amendment was entered (note the statement "Any previously filed unentered amendments will be entered unless applicant instructs otherwise" in the Transmittal) and this Preliminary Amendment was filed. Therefore, the claim amendments made here reflect the prior entry of amendments from September 5, 2007. The "last claim of record" is September 5, 2007.

The claim amendments are fully supported by the original disclosure and, thus, no new matter is added by their entry. Support for a biosensor comprising at least one reporter group attached at one or more of amino acid positions 10, 93 and 183 of a glucose binding protein (GBP) is found in original claim 1. Acrylodan as a reporter group is supported at page 15, lines 18-19, and Table 5 of the specification.

Claims 16-20 and 24-28 were withdrawn from consideration by the Examiner. Their rejoinder and examination in this application after allowance of claim 1 or 15 are requested.

Double Patenting

Claims 1-5 were rejected on the ground of nonstatutory obviousness-type double patenting as being allegedly unpatentable over claims 1-8 of Patent 6,277,627 (the '627 patent). Applicants traverse.

The pending claims are directed to a glucose binding protein with at least one reporter group attached at one or more of positions of 10, 93 or 183. There is no reason provided in the Action for why one of ordinary skill in the art would have attached one or more reporter groups at these positions. The mutations recited in claim 12 of the '627 patent were not made to attach a reporter group. Therefore, it would not have been obvious to attach a reporter group at one or more positions of 10, 93 or 183.

Withdrawal of the double patenting rejection is requested.

35 U.S.C. 102 – Novelty

A claim is anticipated only if each and every limitation as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of Calif.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is claimed. See *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Claims 1 and 3-15 were rejected under Section 102(e) as allegedly anticipated by Amiss et al. (U.S. Patent Application 2003/0134346 or U.S. Patent 6,855,556). Applicants traverse.

It was alleged on page 6 of the Action that Amiss et al. disclose that the reporter group may be attached “throughout the length of the galactose/glucose binding protein” citing to paragraph [0034]. But this is not taught in the indicated paragraph of Amiss et al. Only positions 11, 14, 19, 43, 74, 107, 110, 112, 113, 137, 149, 152, 213, 216, 238, 287, and 292 are disclosed. It was also taught, “The reporter group may be attached to the mutated protein or GGBPs by any conventional means known in the art.” There is no teaching, however, in Amiss et al. of attaching a reporter group at any position along the length of a glucose binding protein as alleged in the Action.

Withdrawal of the Section 102 rejection is requested.

35 U.S.C. 103 – Nonobviousness

To establish a case of prima facie obviousness, all of the claim limitations must be taught or suggested by the prior art. See M.P.E.P. § 2143.03.

Claims 1-15 were rejected under Section 103(a) as allegedly unpatentable over Hellinga (WO 99/34212 or the ‘627 patent). Applicants traverse.

As noted above, the pending claims are directed to a glucose binding protein with at least one reporter group attached at one or more of positions of 10, 93 or 183. See Table 5 at pages 33-34 and 35 of Applicants’ specification. The cited documents do not teach or suggest these specific positions for attaching reporter groups. And there is no

reason provided in the Action for why one of ordinary skill in the art would have attached one or more reporter groups at these specific positions.

In particular, attaching a reporter group at amino acid position 183 provides the unexpected results of decreased binding affinity for glucose and increased fluorescence characteristics. For a person afflicted by diabetes, a biosensor tuned to physiological concentrations of glucose in the millimolar range is a clear advantage, which is taught at page 53, lines 11-20, of the specification. As shown in Table 5, decreased binding affinity is achieved by attaching a reporter group at position 183 of glucose binding protein. See page 35 of the specification. In Table 5, it can also be seen that the fluorescence characteristics ΔI_{std} and ΔR_{max} are desirable. Fig. 5A shows that fluorescence response to log concentrations of glucose is linear. By ratiometry, clinically relevant ranges of glucose may be measured and different clinical states easily distinguished as shown in Fig. 8A. These unexpected results are not taught or suggested by the prior art of record. And there is no reasonable expectation of success to attach a reporter group at position 10, 93 or 183 of glucose binding protein found in the prior art.

Withdrawal of the Section 103 rejection is requested.

Conclusion

Having fully responded to the pending Office Action, Applicants submit that the claims are in condition for allowance and earnestly solicit an early Notice to that effect.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: /Gary R. Tanigawa/
Gary R. Tanigawa
Reg. No. 43,180

901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100